



American Academy of Family Physicians
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Dockets Management
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, MD 20852

August 19, 2002

Subject: OTC Drugs – NDAC Meeting, Sept 19-20, 2002

I am writing on behalf of the American Academy of Family Physicians and its 93,500 members in regard to the upcoming hearings on OTC medications. We support efforts by industry and government to assure the safe use of all pharmaceutical products. In particular, we are writing to communicate our position that acetaminophen has proven to be a safe and efficacious therapeutic agent, when used appropriately.

As you are well aware, acetaminophen is one of the most widely used products in primary care practice. Family physicians, who account for 1 in every 4 patient encounters in the U.S., have recommended this product for many years for a wide variety of patient populations – men and women, children and the elderly – and for many conditions. It is particularly valuable in patients who are unable to tolerate other forms of analgesia. Because this product is so important to our members and their patients, we feel it is important to offer our views.

The safety and efficacy of acetaminophen, when used in appropriate doses, is well established in the scientific literature. We feel it is important that clinicians and the public understand how to use this drug properly, which is why we have taken such efforts as the publication and dissemination of a monograph on the “Appropriate Use of Common OTC Analgesics and Cough and Cold Medications” (copy attached). We also support appropriate labeling of products so that patients can easily determine the doses of the medications they are taking.

We feel that all decisions regarding appropriate use, formulation and dosage should be evidence based. We also have a concern that one possible result of these hearings, and the potential media flurry surrounding them, may be to cause patients to change their analgesics inappropriately to ones that could potentially have undesirable outcomes. This unintended consequence could potentially put patients at risk.

Board Chair

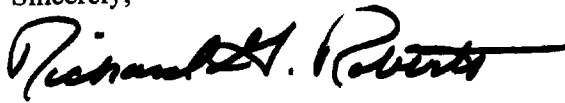
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The American Academy of Family Physicians supports the FDA's mandate to address issues of safety as well as efficacy. We are hopeful that these hearings will focus strictly on well-established scientific evidence and tread carefully in the discussions of one of the most widely used, safe and efficacious medications available to both physicians and patients.

Sincerely,

A handwritten signature in black ink, reading "Richard G. Roberts". The signature is fluid and cursive, with a long horizontal stroke extending from the end.

Richard G. Roberts, MD, JD
Chair, Board of Directors
American Academy of Family Physicians

Attachment: OTC monograph